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Display Date 10-29-03  
Publication Date 10-28-03  
Certifier G. Pinsky

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 870**

**[Docket Nos. 1994N-0418 and 1996P-0276]**

**Medical Devices: Cardiovascular Devices: Reclassification of the Arrhythmia  
Detector and Alarm**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is reclassifying arrhythmia detector and alarm devices from class III to class II (special controls). This device is used to monitor an electrocardiogram (ECG) and to produce a visible or audible signal or alarm when an atrial or ventricular arrhythmia occurs. An atrial or ventricular arrhythmia occurs during a premature contraction or ventricular fibrillation. FDA is reclassifying this device based on new information contained in reclassification petitions regarding the device submitted by the Health Industry Manufacturers Association (HIMA) (now known as Advamed), Quinton Instrument Co., and Zymed Medical Instrumentation. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for this device. FDA is taking this action under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), the Food and Drug Administration Modernization Act

of 1997 (the FDAMA), and the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).

**DATES:** This rule is effective [*insert date 30 days after date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Elias Mallis, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8517, ext. 177.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The act (21 U.S.C. 301 *et. seq.*) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360(e)) established three categories (classes) of devices as a function of the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as “preamendments devices.” FDA classifies these devices after the agency initiates the following procedures: (1) Receives a recommendation from a device classification panel (an FDA advisory committee), (2) publishes the panel’s recommendation for comment, along with a proposed regulation classifying the device, and (3) publishes a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

FDA refers to devices that were not in commercial distribution before May 28, 1976, as “postamendments devices.” These devices are classified

automatically by statute (section 513(f)) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless FDA initiates the following procedures: (1) Reclassifies the device into class I or II, (2) issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the act, or (3) issues, under section 513(i) of the act, an order finding the device as substantially equivalent to a predicate device that does not require premarket approval. As delineated in section 510(k) of the act (21 U.S.C. 360(k)) and under part 870 of the regulations (21 CFR part 870), FDA determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures. Through premarket notification procedures, a person may, without submission of a premarket approval application (PMA), market a preamendments device that has been classified into class III until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Section 513(e) of the act governs reclassification of classified preamendments devices. This section provides that FDA may, by rulemaking, reclassify a device based on “new information.” Under section 513(e) of the act, FDA can initiate a reclassification or an interested person can petition FDA to reclassify a preamendments device. The term “new information,” as used in section 513(e) of the act, includes information developed after the date of the device’s original classification. This information could include a reevaluation of the original data or information from the time of the original classification that was not presented, available, or deemed applicable. (See, e.g., *Holland Rantos v. United States Department of Health, Education, and*

*Welfare*, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn v. Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell v. Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously used by FDA is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell v. Goddard*, *supra*, 366 F.2d at 181; *Ethicon, Inc. v. FDA*, 762 F.Supp. 382, 389–391 (D.D.C. 1991)), or in light of changes in “medical science.” (See *Upjohn v. Finch*, *supra*, 422 F.2d at 951.) Whether data before the FDA are past or new data, the “new information” to support reclassification under section 513(e) of the act must be “valid scientific evidence,” as defined in section 513(a)(3) of the act and § 860.7(c)(2) (21 CFR 860.7(c)(2)) (See, e.g., *General Medical Co. v. FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc. v. FDA*, 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1985)).

FDA relies upon “valid scientific evidence” in the classification process to determine the level of regulation for devices. When reclassifying a device, FDA can only consider valid scientific evidence that is publicly available. Publicly available information excludes trade secret and confidential commercial information, e.g., the contents of a pending PMA. (See section 520(c) of the act (21 U.S.C. 360j(c).) Section 520(h)(4) of the act provides that 6 years after the date FDA has approved an application FDA may, for reclassification of a device, use certain information contained in a PMA. Useable information includes data from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device. This information does not include descriptions of methods of manufacture, product composition, and other trade secrets.

## II. Regulatory History of the Device

In the **Federal Register** of December 13, 2002 (67 FR 76706), FDA proposed to reclassify arrhythmia detector and alarm devices from class III to class II (special controls). These devices are used to monitor an electrocardiogram and to produce a visible or audible signal or alarm when an atrial or ventricular arrhythmia occurs. Concurrently, FDA proposed to separate the identification of arrhythmia detectors and alarms from automated external defibrillators (AEDs). FDA decided to address, at a later date, the possible reclassification of AEDs, devices primarily designed for a different intended use (i.e., to correct an arrhythmia) than the arrhythmia detector and alarm. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of intent to reclassify AEDs.

Also in the **Federal Register** of December 13, 2002 (67 FR 76749), FDA announced the availability of a guidance document that FDA intended would serve as the special control for arrhythmia detector and alarm devices, if FDA reclassified them. FDA gave interested persons until March 13, 2002, to comment on the proposed regulation and guidance document. FDA did not receive any comments on the proposed regulation, but did receive one comment on the guidance document.

## III. Summary of Final Rule

In accordance with § 860.84(g)(2) (21 CFR 860.84(g)(2)) of the regulations, FDA is reclassifying arrhythmia detector and alarm devices into class II. To ensure clarity, FDA is revising the classification of arrhythmia detector and alarm devices by separating these devices from AEDs and establishing a separate classification regulation for AEDs (§ 870.5310). The guidance document entitled “Class II Special Controls Guidance Document: Arrhythmia

Detector and Alarm” will serve as the special control for arrhythmia detector and alarm devices. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of this guidance document. Following the effective date of the final classification rule, any firm submitting a 510(k) premarket notification for the device will need to address the issues covered in the special controls guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

FDA believes that review of performance characteristics and labeling can ensure that acceptable levels of performance for both safety and effectiveness are addressed before marketing clearance. Thus, persons who intend to market this device must submit to FDA a premarket notification submission before marketing the device.

#### **IV. Analysis of Comments and FDA’s Response**

FDA received no comments on the proposed rule. Therefore, FDA is codifying the reclassification and special controls guidance by amending § 870.1025. FDA is also adding a separate regulation for AEDs (§ 870.5310). For the convenience of the reader, FDA is also adding § 870.1 to inform the reader where to find guidance documents referenced in part 870.

#### **V. Environmental Impact**

FDA has determined under 21 CFR 25.34(b) that this reclassification action does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### **VI. Analysis of Impacts**

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded

Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives. If regulation is necessary, a regulatory agency must plot a course that maximizes net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). FDA believes that the final rule is consistent with the regulatory philosophy and principles identified in the Executive order. Additionally, as defined by the Executive order, the final rule does not constitute a significant regulatory action. As a result, the final rule is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of this device from class III to class II will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act. Manufacturers of class III arrhythmia detectors and alarms currently are required to submit premarket notifications. The guidance document reflects existing FDA practice in the review of these premarket notifications. FDA expects that manufacturers of cleared arrhythmia detectors and alarms will not have to take any additional action in response to this rule. This rule will help expedite the review process for any new manufacturers of these devices. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this rule will not have a significant economic impact on a substantial number of small entities. In addition, this rule will not impose

costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

## **VII. Federalism**

FDA has analyzed the final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, FDA has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order. As a result, a federalism summary impact statement is not required.

## **VIII. Paperwork Reduction Act of 1995**

FDA concludes that the final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget, according to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

## **List of Subjects in 21 CFR Part 870**

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 870 is amended as follows:

## **PART 870—CARDIOVASCULAR DEVICES**

■ 1. The authority citation for 21 CFR part 870 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

- 2. Section 870.1 is amended by adding paragraph (e) to read as follows:

**§ 870.1 Scope**

\* \* \* \* \*

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

- 3. Section 870.1025 is revised to read as follows:

**§ 870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm).**

(a) *Identification.* The arrhythmia detector and alarm device monitors an electrocardiogram and is designed to produce a visible or audible signal or alarm when atrial or ventricular arrhythmia, such as premature contraction or ventricular fibrillation, occurs.

(b) *Classification.* Class II (special controls). The guidance document entitled “Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm” will serve as the special control. See § 870.1 for the availability of this guidance document.

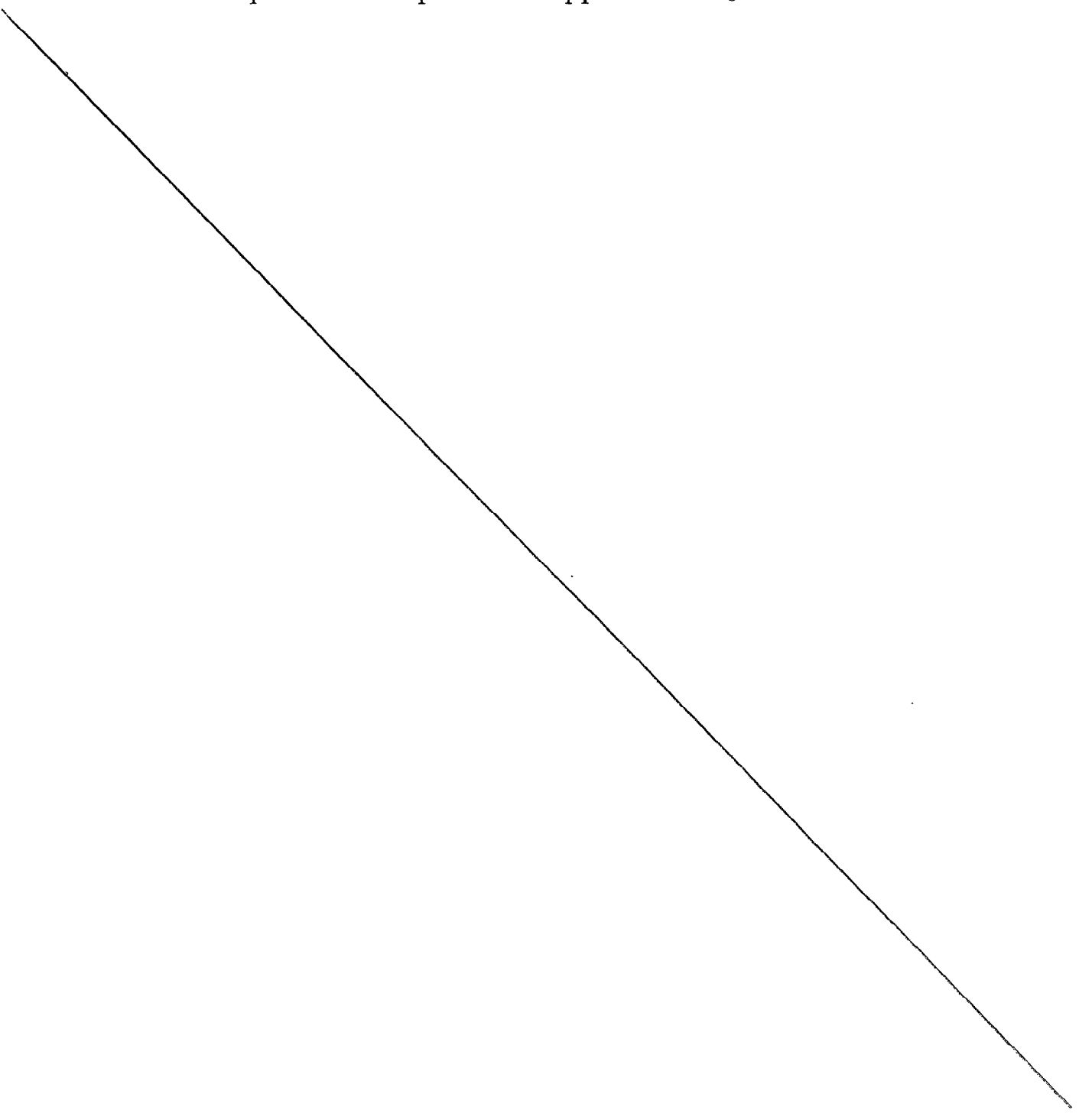
- 4. Section 870.5310 is added to subpart F to read as follows:

**§ 870.5310 Automated external defibrillator.**

(a) *Identification.* An automated external defibrillator (AED) is a low-energy device with a rhythm recognition detection system that delivers into a 50 ohm test load an electrical shock of a maximum of 360 joules of energy used for defibrillating (restoring normal heart rhythm) the atria or ventricles of the heart. An AED analyzes the patient’s electrocardiogram, interprets the cardiac rhythm, and automatically delivers an electrical shock (fully automated AED), or advises the user to deliver the shock (semi-automated or shock advisory AED) to treat ventricular fibrillation or pulseless ventricular tachycardia.

(b) *Classification.* Class III (premarket approval)

(c) *Date PMA or notice of PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.



Dated: 10/2/03  
October 2, 2003.

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[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

**BILLING CODE 4160-01-S**

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